

**Amendments to the Drawings:**

The attached sheet of drawings includes changes to Fig. 14B. This sheet, which includes Fig. 14B, replaces the original sheet including Fig. 14E. In Fig. 14B, reference number 322 has been deleted.

**Attachment: Replacement Sheet**

**Annotated Sheet Showing Changes**

**REMARKS**

Applicant cancelled claims 3 and 4 without prejudice or disclaimer of their subject matter and added new claims 21-32 to further define Applicant's claimed invention.

New claims 21-32 are supported by the specification at least by page 8, lines 3-6 and page 38, line 5 to page 39, line 6; and Figs. 14B and 15. Applicant brings to the attention of the Examiner that new claims 21-32 are claims copied from U.S. Patent No. 6,780,192 to McKay et al. ('192 patent) and correspond to claims 9, 12, 13, and 15-23, respectively, of the '192 patent.

In the Office Action, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) as failing to show every feature of the invention specified in the claims.

Applicant respectfully traverses the Examiner's objection. An access port Intersecting the cavity to receive osteogenic material is shown in Fig. 14B and identified by the reference number 340. As described by Applicant in the specification, "harvested bone is then placed as shown in FIG. 14B, through opening 340 of Implant Bone Loading device 320, where the barrel portion 304 then passes through and is stopped by circular flange 344." (Specification, page 38, lines 5-7). Accordingly, Applicant submits that Fig. 14B shows an access port as recited in the claimed invention. Applicant submits that the objection to the drawings under 37 C.F.R. § 1.83(a) has been overcome.

The Examiner objected to the drawings under 37 C.F.R. § 1.84(p)(5) because they include a reference character not mentioned in the description. In particular, the Examiner contends that reference number 322 is not mentioned in the description.

Applicant amended Fig. 14B to delete reference number 322, thus overcoming the Examiner's objection to the drawings under 37 C.F.R. § 1.84(p)(5).

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner contends that the specification fails to disclose an access port intersecting the cavity to receive osteogenic material. Applicant respectfully traverses the Examiner's rejection.

Independent claim 1 recites an apparatus having "an access port intersecting said cavity to receive said osteogenic material." Applicant discloses an access port

(opening 340 in Fig. 14B) intersecting the cavity to receive osteogenic material. The dictionary definition of the term "intersect" is "to share a common area: OVERLAP." (Merriam-Webster's Collegiate Dictionary, page 612, 10<sup>th</sup> ed. (1999)). The access port disclosed by Applicant "intersects" the cavity because as shown in Fig. 14B, opening 340 shares a common area with the cavity. Accordingly, Applicant submits that the subject matter of independent claim 1 is supported by the disclosure as originally filed.

Independent claim 13 recites a method including the step of "providing the osteogenic material through the access port and onto the fusion device." The Examiner's rejection does not state any reasons as to why the subject matter of independent claim 13 fails to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Applicant submits that independent claim 13 is fully supported by Applicant's disclosure. As described by Applicant in the specification, trephine 300 may be used to extract a core of bone. (See Specification, page 37, lines 23-25; Fig. 14A). Once the bone has been extracted, "harvested bone is then placed as shown in FIG. 14B, through opening 340 of Implant Bone Loading device 320, where the barrel portion 304 then passes through and is stopped by circular flange 344." (Specification, page 38, lines 5-7; Fig. 14B). The harvested bone is then ejected directly into the spinal implant. (Specification, page 38, lines 29-30). Applicant submits that the specification supports a method including the step of "providing the osteogenic material through the access port and onto the fusion device" as recited in independent claim 13.

Applicant respectfully submits that the Examiner's rejection of claims 1-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement has been overcome.

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses the Examiner's rejection. Applicant submits that a person reasonably skilled in the art could make or use the invention from the disclosure coupled with information known in the art without undue experimentation. Applicant respectfully disagrees with the Examiner's

contention that the specification does not reasonably provide enablement for an access port intersecting the cavity to receive osteogenic material. Applicant discloses an access port (opening 340) "intersecting" the cavity to receive osteogenic material in Fig. 14B. Applicant respectfully submits that a person reasonably skilled in the art would appreciate at least from Fig. 14B and the description corresponding thereto how to make or use the access port recited in independent claim 1 of Applicant's claimed invention. Further, Applicant respectfully submits that the Examiner's contention is not applicable to independent claim 13, which does not recite nor require the access port to intersect the cavity.

The Examiner contends that the specification does not disclose osteogenic material being inserted through an access port intersecting the cavity. As best understood by Applicant, the Examiner's contention appears directed toward the method of independent claim 13, which recites the step of "providing the osteogenic material through the access port and onto the fusion device." Applicant respectfully submits that the Examiner's contention is unsubstantiated because (1) the Examiner is focusing on the subject matter disclosed rather than the subject matter enabled and (2) independent claim 13 does not recite nor require the access port to intersect the cavity. (See MPEP § 2164, "[t]he enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement.") Moreover, the Examiner states that the specification is "enabling for inserting osteogenic material through a proximal opening that [is] parallel with the cavity of the packing device." (Office Action, page 4, paragraph 1). Applicant respectfully submits that, as admitted by the Examiner, the specification is enabling for "inserting osteogenic material through a proximal opening" (opening 340), thus the specification is also enabling for "providing the osteogenic material through the access port" as recited in claim 13. Accordingly, Applicant submits that the subject matter of independent claim 13 is enabled.

Applicant respectfully submits that the Examiner's rejection of claims 1-20 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement has been overcome.

The Examiner rejected claims 1-15 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,489,307 to Kuslich et al. ("Kuslich"). Applicant respectfully traverses the Examiner's rejection for at least the following reasons.

**A. Kuslich does not disclose an osteogenic material packing device.**

Independent claim 1 recites "an osteogenic material packing device for packing osteogenic material onto a fusion device." Independent claim 13 recites a method including the step of "Inserting the fusion device into a cavity of a packing device." Kuslich teaches passing an implant through a drill tube 92. (Kuslich, col. 13, lines 33-36; Fig. 62). Once the implant is fully seated in the implantation space between the vertebral bodies, Kuslich teaches removing the drill tube and packing the implant with bone graft material. (Kuslich, col. 13, lines 42-44, 50, and 51). As an alternative, Kuslich teaches that drill tube 92 may be left in place with the graft material being inserted through the tube into the implant that is in the implantation space. Thus, Kuslich teaches that the implant is loaded with graft material whether or not the drill tube is used. The drill tube taught by Kuslich is not an essential component used to load the implant with graft material.

The drill tube taught by Kuslich is incapable of performing as "an osteogenic material packing device" because no structure is provided to retain the implant therein so that the implant can be loaded while in the device. Drill tube 92 permits the implant to pass completely therethrough and into the spine. (See Kuslich, Fig. 62). Any loading of the implant with graft material occurs in the implantation space after the implant is outside the drill tube. Accordingly, the drill tube taught by Kuslich is incapable of functioning as an osteogenic packing material device as recited in independent claims 1 and 13 of Applicant's claimed invention.

**B. A person of ordinary skill in the art would not consider the Kuslich drill tube to be "an osteogenic material packing device."**

Applicant submits that a person of ordinary skill in the art would read the disclosure of Kuslich and conclude that drill tube 92 is not "an osteogenic material

packing device." Kuslich teaches that the drill tube is used for inserting instruments and implants therethrough. The drill tube taught by Kuslich is not configured to "receive" the fusion device as recited in independent claim 1. As defined in the dictionary, the term "receive" means "to act as a receptacle or container for <the cistern receives water from the roof>." (Merriam-Webster's Collegiate Dictionary, page 975, 10<sup>th</sup> ed. (1999)). Applicant submits that a person of ordinary skill in the art would recognize the drill tube taught by Kuslich as not being configured to receive (or act as a receptacle for) a spinal fusion device.

**C. The Examiner is using impermissible hindsight.**

It is respectfully submitted that the Examiner is using impermissible hindsight by piecing together the rejection of the present claims over Kuslich from Applicant's own teachings in the specification. (See MPEP § 2141.01(III), page 2100-98, col. 2 (May 2004) ("[i]t is difficult but necessary that the decision-maker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." (citation omitted)). Applicant respectfully submits that the rejection was not framed with the mind of one skilled in the art presented only with the references and then-commonly accepted wisdom in the art, but with the guidance of Applicant's teachings. It is therefore submitted that a *prima facie* case of obviousness has not been established.

Applicant submits that independent claims 1, 13, and 21 are patentable and that dependent claims 4-12, 14-20, and 22-32 dependent from one of independent claims 1, 13, and 21, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1068.

Respectfully submitted,

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